

**REMARKS/ARGUMENTS**

Claims 1-29, 31-37, 39-43 and 45-50 are pending. By this amendment, claims 1, 17, 29, 32-36, 39-42 and 45-48 are amended and claims 30, 38 and 44 are canceled.

Reconsideration in view of the above amendments and the following remarks is respectfully requested.

The Office Action asserts that newly submitted claims 36, 37, 43, 49 and 50 are directed to an invention that is independent or distinct from the invention originally claimed because they are allegedly drawn to a species that includes a vent assembly comprising a cylinder and a sleeve to be attached below an elbow, which can be seen in figure 6. The Office Action asserts that the previously elected species is directed to a vent assembly found on the mask or on the elbow and that claims 36, 37, 43, 49 and 50 are withdrawn as directed to a non-elected invention.

However, it is noted that the specification indicates that the vent assembly of Fig. 6 is formed as part of swivel elbow 120. See [0060]. Thus, claims 36, 37, 43, 49 and 50 are drawn to the previously elected species (a vent assembly found on the elbow) and the requirement to make an election is improper. Reconsideration and withdrawal of the requirement to make an election is requested.

The Office Action objects to the drawings under 37 C.F.R. 1.83(a) and to the amendment filed 3/24/10 under 35 U.S.C. § 132(a) because the drawings and amendments to the specification received on 3/24/10 allegedly introduce new matter which was not present in the originally filed specification or drawings, and because the drawings must show the “nozzle elements”. These objections are respectfully traversed.

The amendment to the drawings and the amendment to the specification filed with the Amendment on 3/24/10 do not introduce new matter. The patient interface frame 210 is illustrated in Figs. 11a-14, with Fig. 14 revised to illustrate the nozzles 211. A corresponding amendment is made to the specification referring to the nozzles. These revisions do not constitute new matter as one of ordinary skill in the art would understand the nozzles so positioned. This type of nozzle configuration is well known, as shown in US Pat. 7,318,437, which has a common inventor with the present application. See for example Figs. 61, 76B, etc. of the '437 patent, which show a substantially similar frame as shown in Fig. 11a-14 of the present application, both of which frames are constructed to receive a pair of nozzles. Approval of the amendment to the drawings and specification is requested.

The Office Action rejects claims 4, 15, 16, 25 and 26 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Office Action asserts that the specification does not disclose how nozzle elements are part of a mask assembly. However, as explained above, this type of nozzle configuration is well known, as shown in U.S. Pat. 7,318,437, which has a common inventor with the present application. See for example Figs. 61, 76B, etc. of the '437 patent, which show a substantially similar frame as shown in Fig. 11a-14 of the present application, both of which frames are constructed to receive a pair of nozzles.

The Office Action rejects claims 29, 33, 40 and 46 under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

Claim 29 has been amended to recite “a” flow of exhaled gas. Regarding claims 33, 40 and 46, the recitation of “wherein a number of the plurality of first vent holes is less than a number of the plurality of second vent holes” does further limit the claims from which they depend. The first and second plurality of vent holes could both be a same number of vent holes, which would not meet the noted feature of claims 33, 40 and 46, but would still meet the limitation of the claims from which they depend. Withdrawal of the rejection is requested.

The Office Action rejects claims 1 and 4 under 35 U.S.C. § 102(b) as over Humphries (U.S. Pat. 1,125,542). This rejection is respectfully traversed.

The Office Action asserts that Humphries discloses what is inherently a nasal mask assembly in that it covers the nostrils of a patient, a frame (a, b), a cushion in the form of two nozzle elements (c) to be inserted into the nostrils of a user, and a vent assembly including a first vent (s) and a second vent (u) wherein a clip (o) slides around the frame to select between the two vents, referring to page 2, lines 4-15.

However, Humphries does not disclose a vent assembly including a first vent having a plurality of first vent holes with a first venting characteristic, a second vent having a plurality of second vent holes with a second venting characteristic, and a selector to switch a flow of exhaled gas from the patient to the first vent holes or the second vent holes, as recited in claim 1. Humphries instead discloses a combined air admission and expiration valve having a cylinder *n* opening upward from tube *a*, and covered by a cap *o* fitting over it. The top of the cylinder *n* is formed as a valve seat with a diaphragm valve *p* adapted to close the entry into the top of the cylinder, and which is kept normally on its seat by means of a light spring *r*. Apertures *s* are made in the wall of the cap above the level of the valve so that as the patient exhales through the

nostrils, the exhalations lift up valve *p* and the exhalations escape through the apertures *s*. When exhalation ceases, the valve reseats itself and prevents entry of air through it. See page 1, col. 2, lines 93-111.

In contrast, ports *t* and *u* formed in the cylinder and in the cap beneath the valve *p* allow entry of air into the tube by rotation of the cap making the ports coincident with one another. See page 2, col. 1, lines 4-15. Thus, Humphries does not disclose a vent assembly including a first vent having a plurality of first vent holes, a second vent having a plurality of second vent holes, and a selector to switch a flow of exhaled gas from the patient to the first vent holes or the second vent holes, as recited in claim 1 of the application.

Further, even if the ports *u* formed in the cylinder beneath the valve *p* could be considered to be first vent holes (even though Humphries indicates they allow entry of air into the tube), there is no indication in Humphries that apertures *s* in the wall of the cap above the level of the valve would have a different venting characteristic from the ports *u* formed in the cylinder beneath the valve *p*. Humphries therefore does not disclose a first vent having a plurality of first vent holes with a first venting characteristic, and a second vent having a plurality of second vent holes with a second venting characteristic different from the first venting characteristic, as recited in claim 1.

Regarding claim 4, the Office Action asserts that Humphries discloses a clip (*o*) that slides around the frame to select between the two vents. However, Humphries discloses a cap *o* placed over cylinder *n*, with ports *t* and *u* formed in cylinder *n* and in the cap *o* beneath the valve *p*, that allows entry of air into the tube by rotation of the cap when the ports are made coincident with one another. Humphries does not disclose a selector that includes a clip that is slidable with

respect to the frame to select between the first and second vents. Rotation of the cap allows lining up of ports *t* and *u*, but does not disclose a slidable clip that selects between the first and second vents, to switch the flow of exhaled gas from the patient between the first and second vents, as recited in claim 4. For the above reasons, claim 4 of the application is not anticipated by Humphries. Withdrawal of the rejection is requested.

The Office Action rejects claims 1-3, 5-26, 29-35, 38-42, and 44-48 under 35 U.S.C. § 103(a) over Bauman (U.S. Patent 4,821,713) in view of Gradon (U.S. Patent 6,662,803). This rejection is respectfully traversed.

Regarding claims 1 and 17, the Office Action asserts that Bauman discloses a mask assembly comprising a vent assembly including a first vent 127, a second vent 126 and a selector switch 121 to switch the flow of exhaled gas from the patient between the first and second vents, referring to col. 5, lines 3-20.

However, Bauman discloses that the rotor or rotatable cap 121 is part of air bleed means 120, for controlling the amount of air passing to the patient in the mask. See col. 4, line 53 through col. 5, line 20. The rotatable cap 121 is not a switch to switch the flow of exhaled gas from the patient to the first vent holes or the second vent holes, as recited in independent claims 1 and 17 of the application, but instead is used to control the amount of air delivered to the patient. The Office Action asserts that at the onset of exhalation, a flow of gas would flow through the air bleed means 120 before closing of valve 32. However, Bauman indicates that the flap valves 31a and 32a are normally closed flap valves, which will prevent exhalation air from entering the air bleed means 120.

Further, the resuscitator of Bauman utilizes re-entrant duct 70 defining air discharge port 71 in communication with air outlet 19 for discharging air exhaled by the patient. See col. 3, line 66 through col. 4, line 8. The air discharge port 71 does not disclose a switch to switch the flow of exhaled gas from the patient between the first and second vents, as recited in independent claims 1 and 17. Instead, the one and only air discharge port 71 is fixed. Further, flap valves 31 and 32 isolate air bleed means 120 from the patient during exhalation, specifically "...upon exhalation by the patient, flap valve 32 being closed against seat 32b. Exhaled lung air then escapes via duct 70." See col. 3, line 66- col. 4, line 3 and col. 3, lines 13-24. As a result, no exhaled gases are intended to pass through air bleed means 120. Gradon does not solve the above deficiencies of Bauman regarding claims 1 and 17.

Even if the air bleed means 120 would allow exhalation air to enter, which it does not, Bauman does not disclose a vent assembly including a first vent having a plurality of first vent holes with a first vent characteristic, a second vent having a plurality of second vent holes with a second vent characteristic different from the first venting characteristic, and a selector to switch a flow of exhaled gas from the patient to the first vent holes or the second vent holes, as recited in claims 1 and 17 of the application. The vent openings 125-127 are selectively and individually brought into registration with vent opening 123. See col. 5, lines 3-6. When vent opening 123 is lined up with any individual one of vent openings 125-127, there is formed a single vent (formed by vent opening 123 lined up with a selected one of vent openings 125, 126, or 127). The Bauman vent openings do not include a first vent having a plurality of first vent holes or a second vent having a plurality of second vent holes, as recited in claims 1 and 17 of the application.

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For the above reasons, claims 1 and 17 and all claims dependent therefrom would not have been obvious over Bauman in view of Gradon.

In addition, neither Bauman nor Gradon disclose a vent assembly provided to the frame having a first vent portion with a first flow capacity and a second vent portion with a second flow capacity, the first vent portion and the second vent portion for venting exhaled gases from the patient, and a slidable selector to switch between the first and second vent portions, as recited in independent claim 29. The rotatable cap 121 is part of air bleed means 120, for controlling the amount of air passing to the patient in the mask, and is not a first vent portion and a second vent portion for venting exhaled gases from the patient. Gradon does not solve these deficiencies. For these reasons, claim 29 and all claims dependent therefrom would not have been obvious over Bauman in view of Gradon. Withdrawal of the rejection is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140 under Order No. PTB-4398-537.

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Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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